K063822

510(k) Summary of Safety and Effectiveness for the HIPSTAR Femoral Stem

JAN 25 2007

Proprietary Name:	HIPSTAR Femoral Stem
Common Name:	Total Hip Joint Replacement Prosthesis
Classification Name and Reference	Hip joint, metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prostheses, 21 CFR §888.3353 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 21 CFR §888.3358
Regulatory Class:	Class II
Device Product Code:	87 MEH - prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate 87 LZO - prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented 87 LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented
For Information contact:	Tiffani Rogers Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, New Jersey 07432 Phone: (201) 831-5612 Fax: (201) 831-6038 E-Mail: Tiffani.Rogers@stryker.com
Date Summary Prepared:	January 25, 2007

Device Description

The Hipstar Femoral Stem is a straight hip stem manufactured from titanium alloy, TMZF™. The Hipstar hip features a proximal, lateral flare for rotational stability, with a narrow distal stem for implant stability. The body of the stem, with the exception of the trunnion, neck and distal tip, is iron grit blasted for increased bone to implant interface. The subject hip stem has a 127° neck angle.

Intended Use:

The HIPSTAR hip stem is a sterile, single-use device intended for total hip arthroplasty.

Indications

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- rheumatoid arthritis (excepting the Osteolock™ HA Acetabular Cup and Peri-Apatite coated prostheses);
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and,
- treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques
- intended for cementless fixation.

Substantial Equivalence:

The subject Hipstar femoral stem is a modification to the Hipstar stem cleared in K051223. The determination of the substantial equivalence of the Hipstar hip stem is based on its similarities in intended use, design and sterilization to the previously cleared Hipstar femoral hip stem (K051223 cleared March 06, 2006).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stryker Howmedica Osteonics Corporation
% Ms. Tiffani Rogers
Regulatory Affairs Specialist
Stryker Orthopaedics
325 Corporate Drive
Mahwah, New Jersey 07430

JAN 25 2007

Re: K063822
Trade/Device Name: HIPSTAR Femoral Stem
Regulation Number: 21 CFR 888.3358, 21 CFR 888.3353
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO, MEH
Dated: December 21, 2006
Received: December 22, 2007

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Hipstar™ Hip Stem

Indications

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- rheumatoid arthritis (excepting the Osteolock™ HA Acetabular Cup and Peri-Apatite coated prostheses);
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and,
- treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Prescription Use ___X___ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K063822